

**STERILE WATER - water injection, solution**  
**BAXTER HEALTHCARE CORPORATION**

**DESCRIPTION**

Sterile Water for Injection, USP is sterile, nonpyrogenic, distilled water in a Pharmacy Bulk Package. A Pharmacy Bulk Package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for intravenous infusion. No antimicrobial or other substance has been added. pH 5.5 (5.0 to 7.0). Osmolarity 0 mOsmol/L (calc.).

The Viaflex<sup>®</sup> plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146<sup>®</sup> Plastic). Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

**CLINICAL PHARMACOLOGY**

Sterile Water for Injection, USP is used for fluid replacement only after suitable admixing to approximate isotonicity.

**CONTRAINDICATIONS**

Sterile Water for Injection, USP is a hemolytic agent due to its hypotonicity. Therefore, it is contraindicated for intravenous administration without admixing.

**WARNINGS**

**This solution is for compounding only, not for direct infusion.**

**WARNING:** This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 µg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

**PRECAUTIONS**

Do not use unless solution is clear and seal is intact.

Drug product contains no more than 25 µg/L of aluminum

**Pediatric Use**

Safety and effectiveness have been established in pediatric patients. However, in neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

**ADVERSE REACTIONS**

The administration of a suitable admixture of prescribed drugs may be associated with adverse reactions because of the solution or the technique of administration including febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia. If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

**DOSAGE AND ADMINISTRATION**

Following suitable admixture of prescribed drugs, the dosage is usually dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations. See directions accompanying drugs.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions where possible.

Sterile Water for Injection, USP in the Pharmacy Bulk Package is intended for use in the preparation of sterile, intravenous admixtures. Additives may be incompatible with the fluid withdrawn from this container. Complete information is not available.

Those additives known to be incompatible should not be used. Consult with pharmacist, if available. When compounding admixtures, use aseptic technique. Mix thoroughly. Do not store any unused portion of Sterile Water for Injection, USP.

## Directions for use of Viaflex® Plastic Pharmacy Bulk Package Container

### To Open

Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly, if leaks are found, discard solution as sterility may be impaired.

For compounding only, not for direct infusion.

### Preparation for Admixing

1. The Pharmacy Bulk Package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

2. Suspend container from eyelet support.

3. Remove plastic protector from outlet port at bottom of container.

4. Attach solution transfer set. Refer to complete directions accompanying set.

Note: The closure shall be penetrated only one time with a suitable sterile transfer device or dispensing set which allows measured dispensing of the contents.

5. Viaflex® containers should not be written on directly since ink migration has not been investigated. Affix accompanying label for date and time of entry.

6. Once container closure has been penetrated, withdrawal of contents should be completed without delay. After initial entry, maintain contents at room temperature (25°C/77°F) and dispense within 4 hours.

### HOW SUPPLIED

Sterile Water for Injection, USP is supplied in a Viaflex® plastic Pharmacy Bulk Package container as follows:

2000 mL	2B0306	NDC 0338-0013-06
3000 mL	2B0307	NDC 0338-0013-08
5000 mL	2B0309	NDC 0338-0013-29

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F).

### Baxter Healthcare Corporation

Clintec Nutrition Division

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Distributed in Canada by

### Baxter Corporation

Toronto, Ontario, Canada Deerfield, IL 60015 USA

PACKAGE LABEL.PRINCIPLE DISPLAY PANEL

LOT

EXP

2B0309

NDC 0338-0013-29

5000 mL

DIN 02014882

4500

**Sterile Water  
For Injection USP**

4000

**Pharmacy Bulk Package  
Not For Direct Infusion**

3500

**Rx Only**

NO ANTIMICROBIAL OR OTHER SUBSTANCE HAS BEEN ADDED  
pH 5.5 (5.0 TO 7.0) OSMOLARITY 0 mOsmol/L (CALC)

3000

STERILE NONPYROGENIC

CONTAINS NO MORE THAN 25 µg/L OF ALUMINUM

ADDITIVES MAY BE INCOMPATIBLE WITH THE FLUID  
WITHDRAWN FROM THIS CONTAINER CONSULT WITH  
PHARMACIST IF AVAILABLE WHEN COMPOUNDING  
ADMIXTURES USE ASEPTIC TECHNIQUE  
MIX THOROUGHLY DO NOT STORE

2500

DOSAGE ADMIX FOR INTRAVENOUS ADMINISTRATION  
AS DIRECTED BY A PHYSICIAN SEE ACCOMPANYING  
DIRECTIONS FOR USE ONCE CONTAINER CLOSURE  
HAS BEEN PENETRATED WITHDRAWAL OF  
CONTENTS SHOULD BE COMPLETED WITHOUT  
DELAY AFFIX ACCOMPANYING LABEL FOR DATE  
AND TIME OF ENTRY DISPENSE CONTENTS WITHIN  
4 HOURS AFTER INITIAL ENTRY

2000

CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH  
MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS  
ARE FOUND DO NOT USE UNLESS SOLUTION IS  
CLEAR AND SEAL IS INTACT

1500

STORE UNIT IN MOISTURE BARRIER OVERWRAP  
AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY  
TO USE AVOID EXCESSIVE HEAT SEE INSERT

**VIAFLEX CONTAINER**

**PL 146 PLASTIC**

1000

**Baxter**

**BAXTER HEALTHCARE CORPORATION**  
CLINTEC NUTRITION DIVISION  
DEERFIELD IL 60015 USA  
MADE IN USA

DISTRIBUTED IN CANADA BY  
**BAXTER CORPORATION**  
TORONTO ONTARIO CANADA

BAXTER PL 146 AND VIAFLEX ARE TRADEMARKS OF BAXTER INTERNATIONAL INC

500

Sterile Water for Injection Container Label

LOT EXP

2B0309 5000 mL

NDC 0338-0013-29 DIN 02014882

Sterile Water

For Injection USP

Pharmacy Bulk Package

Not For Direct Infusion

**Rx Only**

NO ANTIMICROBIAL OR OTHER SUBSTANCE HAS BEEN ADDED

pH 5.5 (5.0 TO 7.0) OSMOLARITY 0 mOsmol/L (CALC)  
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VIAFLEX CONTAINER PL 146 PLASTIC

**BAXTER**

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CLINTEC NUTRITION DIVISION  
DEERFIELD IL 60015 USA  
MADE IN USA

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BAXTER CORPORATION  
TORONTO ONTARIO CANADA

STERILE WATER FOR INJ, USP FOR DRUG DILUENT USE ONLY

SECONDARY BAR CODE

(17) YYMM00 (10) XXXXX

PRIMARY BAR CODE

(01) 50303380013291  
2B0309

VIAFLEX CONT  
2-5000ML

LOT XXXXX  
EXP XXXXX

Sterile Water for Injection Carton Label

STERILE WATER FOR INJ, USP FOR DRUG DILUENT USE ONLY  
VIAFLEX CONT  
2-5000ML  
SECONDARY BAR CODE  
(17) YYMM00 (10) XXXXX

PRIMARY BAR CODE  
(01) 50303380013291  
LOT XXXXX  
EXP XXXXX  
2B0309